REMARKS

Claims 1-40 were pending in the application. Claims 9 and 35-40 were withdrawn from consideration and are now canceled. Claims 1, 2, 10, 11, 20-25, 31-34 have been amended. Claims 26-29 have been canceled and new claims 41-50 have been added.

Claims 1, 2, and 20 stand rejected under 35 U.S.C. §102(e) as anticipated by Kokish et al. There are two Kokish et al. references cited in this application. It is assumed that the Examiner is referring to U.S. Patent Number 6,485,500 which discloses multiple inflatable balloons coupled to multiple concentric catheters.

Independent claims 1 and 20 have been amended, but not to overcome the Examiner's rejection. The amendment to claims 1 and 20 actually broaden their scope slightly by replacing the term "self-expanding balloon" with the term "self-expanding element". Although the Examiner states that Kokish et al. discloses a self-expanding balloon, it appears that all of the balloons disclosed in Kokish et al. are inflatable balloons. Thus, Kokish et al. cannot anticipate claims 1 and 20 as originally presented or as amended. Furthermore, there is no suggestion in the art to modify Kokish et al. to provide that one of the balloons be self-expanding.

Claims 15-19 stand rejected under 35 U.S.C. §102(b) as anticipated by O'Donnell.

Independent claim 15 is drawn to a catheter coupled to a drug reservoir and dispensing means which is "adapted to automatically dispense the drug from the reservoir into the lumen of the catheter as the catheter is moved through a blood vessel." O'Donnell discloses an automatic fluid dispenser coupled to a catheter which can be used to dispense drugs. However, O'Donnell does not teach or suggest the quoted portion of independent claim 15. Thus, claims 15-19 are neither anticipated nor rendered obvious over O'Donnell.

Claim 24 stands rejected under 35 U.S.C. §102(b) as anticipated by Zacca et al. Independent claim 24 has been amended to replace the term "self-expanding balloon" with the term self-expanding element". The claim as amended includes a first catheter having a self-expanding element coupled to its distal end where the element has an abrasive outer surface. Zacca et al. discloses catheter having a "variably expandable abrasive tip coil." The expandable abrasive tip coil disclosed by Zacca et al. is not self-expanding. Zacca et al. carefully describes several different apparatus (a piston, a bellows, an internal coil, and an inflatable balloon) which are used to expand the coil. There is no suggestion that the coil could be made self-expanding. In fact, the teaching of several different apparatus for expanding

the coil is a strong suggestion that it can not or should not be made self-expanding. Thus, claim 24 is neither anticipated nor rendered obvious over Zacca et al.

Claims 26-34 stand rejected under 35 U.S.C. §102(e) as anticipated by Farley et al. There are four Farley et al. references cited in the application. It is assumed that the Examiner is referring to U.S. Patent Number 6,398,780.

Claims 26-29 have been canceled and replaced with claims 41-46. Independent claim 41 requires delivering a sclerosing agent proximal to the occlusion device. Farley et al. discloses delivering a sclerosing agent in between two electrodes, one of which is a balloon 64 and the other of which is a plurality of bowable members or arms 76. The balloon electrode 64 may be considered an occlusion device but the arms 76 do not occlude the blood vessel. It should be noted that the terms proximal and distal are used in different ways in the art. Some writers use the term proximal to mean close to the patient's heart and the word distal to mean distant from the patient's heart. Other writers including the authors of the instant application and the Farley et al. reference use the word proximal to mean close to the medical practitioner and the word distal to mean distant from the medical practitioner. It is clear that Farley et al. discloses dispensing fluid distal to the balloon electrode 64. Thus, Farley et al. does not anticipate claims 41-46. Moreover, if one were to

dispense a sclerosing agent proximal to the balloon electrode 64 in Farley et al., it would defeat the intention of the Farley et al. device which is to sclerose between two electrodes. Therefore, claims 41-46 are not obvious over Farley et al.

Independent claim 30 includes the method step of "dispensing the intravascular drug through the first catheter while moving the first catheter from the first location to a second location as the first catheter is at least partially pulled out of the incision". The Examiner has not addressed this step and it is neither taught nor suggested by Farley et al. Therefore claims 30-34 are patentable over Farley et al.

Claims 3-8 and 10-14 stand rejected under 35 U.S.C. §103(a) as obvious over Kokish et al. in view of O'Donnell and Hasson. Each of these claims depend directly or indirectly from claim 1 and the remarks made above regarding claim 1 apply to this rejection as well. In framing this rejection, the Examiner has only referred to the provisions of claims 6 and 10. Thus, the provisions of claims 3-5, 7, 8 and 11-14 have not been addressed and any next rejection of these claims cannot properly be made final. The Applicant can not be forced to guess why the Examiner rejected these claims.

Turning to the stated rejection which refers to locking means (claim 7) and drug dispenser (claim 10), the Examiner states that

Hasson discloses a locking means and O'Donnell discloses a drug dispenser. As to the combination of Kokish et al. with Hasson, the Examiner states that the combination "would have been considered an obvious design choice".

An "obvious design choice" is not a statutory rejection. There is no law or rule regarding the grounds for making such a rejection. However, the MPEP instructs Examiners that "if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." See MPEP §2144.04.

Although the Examiner did not refer to any particular legal decision having facts similar to the instant application, MPEP §2144.04 provides seven examples of when a claim may be considered prima facie obvious in view of a prior legal decision. These examples are: (1) aesthetic design change, (2) elimination of a step or an element and its function, (3) automating a manual activity, (4) change in size, shape, or sequence of adding ingredients, (5) making portable, integral, separable, adjustable, or continuous, (6) reversal, duplication, or rearrangement of parts, and (7) purifying an old product. None of these seven examples immediately suggests the facts of the present application.

In addition, the combination of Hasson with Kokish et al. is unlikely because they are related to entirely different subjects. Kokish et al. is concerned with an emboli protection system which is used during angioplasty. Hasson is concerned with a vaginal stabilization cannula which is not likely to have any application in the treatment of arteries. Further, the rejected claims require that the locking means lock the location of two catheters relative to each other. The locking means in Hasson does not perform this function.

As to the combination of Kokish et al. with O'Donnell, the Examiner states that the combination "would have been considered another obvious design alternative". Thus, the discussion above regarding MPEP §2144.04 applies to this rejection as well. Moreover, even if there were incentive to combine these references, the combination would not result in claim 10 which provides that the drug dispenser is "adapted to automatically dispense the drug from the reservoir into the fluid delivery means as said second catheter tube is moved through a blood vessel".

Claims 21-23 stand rejected under 35 U.S.C. §103(a) as obvious over Kokish et al. in view of Sheridan and Zacca et al. These claims depend from claim 20 and the remarks made above regarding claim 20 apply to this rejection as well.

Claim 21 specifies that the self-expanding balloon is composed of spring wires and a thin membrane coupled to the wires. Claim 22 specifies that the self-expanding balloon includes an abrasive outer surface. Claim 23 specifies that self-expanding balloon is made of plastic. The Examiner rejects all of these three claims in two sentences by stating that Sheridan discloses a balloon made of plastic, that Zacca et al. discloses a balloon made of wires having an abrasive surface, and that any combination of these references with Kokish et al. "would have been considered obvious design alternatives."

As argued above, the "obvious design choice" incentive to combine references is improper and the Examiner has not met his burden of citing a specific teaching in the art that suggests the combination of the references. Moreover, even if the references were combined with impunity, the combination would not result in a self-expanding balloon as none of the references teaches a self-expanding balloon. In addition, the combination of Zacca et al. with Sheridan in order to obtain the balloon of claim 21 would destroy the functionality of Zacca et al. by covering the abrasive surface with plastic.

Claim 25 stands rejected under 35 U.S.C. §103(a) as obvious over Kokish et al. in view of Wysgala et al. Claim 25 depends from claim 24 and the remarks made above regarding claim 24 apply to this rejection as well.

Claim 25 further specifies that "at least one of said first catheter tube and said self-expanding balloon includes pores, and said first catheter tube is adapted to receive and deliver an intravascular drug to said pores." In rejecting claim 25, the Examiner states that Wysgala et al. discloses an expandable balloon with an abrasive surface and that the combination with Kokish et al. would have been "an obvious design alternative." Clearly, the Examiner has confused claim 25 with claim 22 or 24. Thus, claim 25 has not been properly rejected and any next rejection of claim 25 can not be made final.

Assuming that the Examiner intended to reject claim 25 over Wysgala et al. in view of Kokish et al., any combination of these references would still not result in a self-expanding balloon as required by independent claim 24 from which claim 25 depends.

A supplemental information disclosure statement is being filed simultaneously herewith to disclose additional prior art which has recently come to the attention of the applicant. It is believed, however, that none of art cited adversely impacts on the patentability of the claims.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is

invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

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